



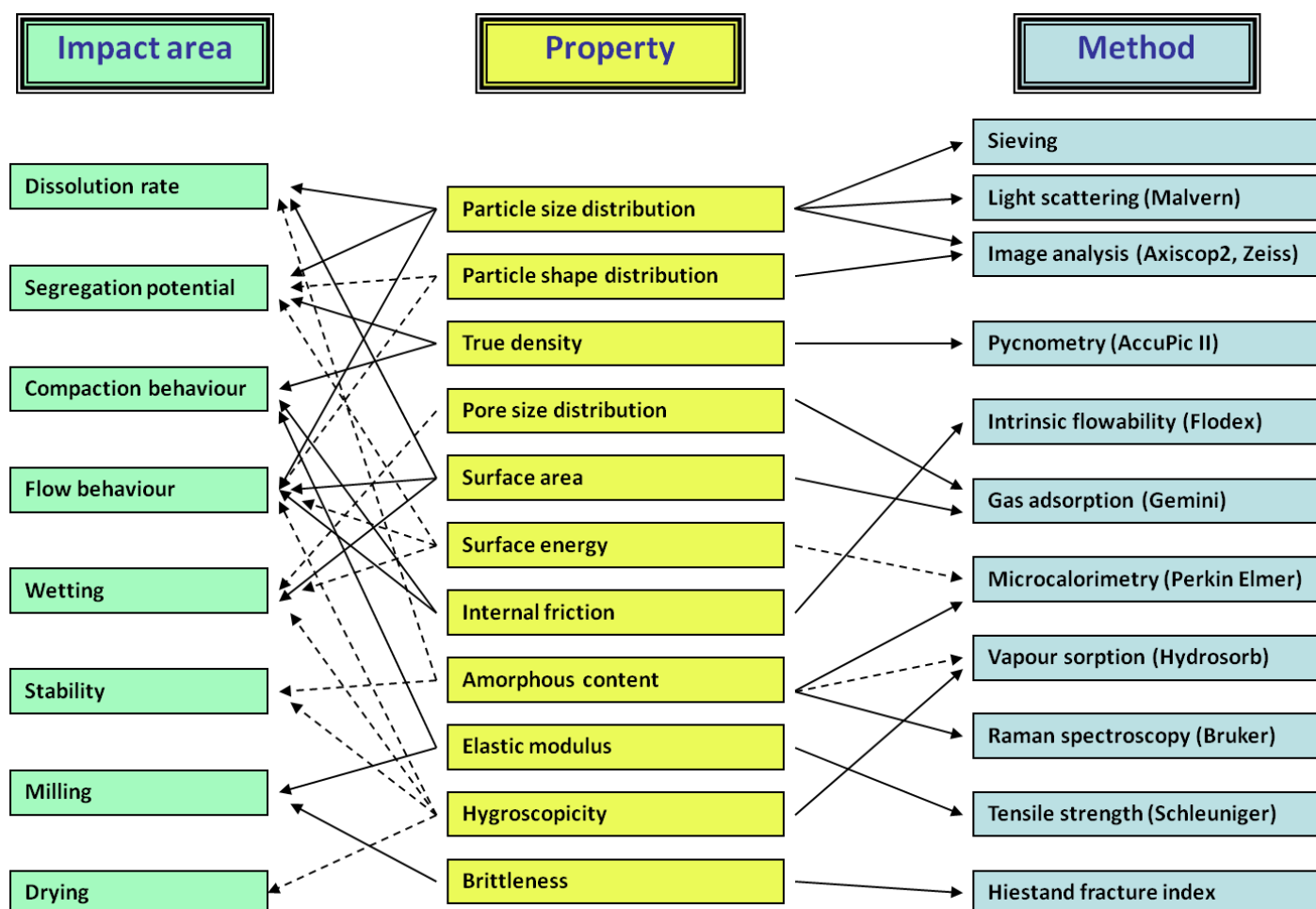
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PHARMACEUTICAL DEVELOPMENT SERVICE

Solid state characterization and preformulation

RESEARCH & DEVELOPMENT DEPARTMENT

Solid state characterization: a knowledge base



Solid and semi-solid dosage forms continue to predominate the arena of pharmaceutical products. It is essential that preformulation scientists utilize their limited time and resources wisely to maximize productivity.

Solid state characterization is the foundation of a knowledge base that leads ultimately to the development of a stable, efficacious dosage form.



"Supposing is good, but finding out is better"
(M. Twain)



Micrometrics, Morphology & Microscopy



Malvern Mastersizer 2000

Type of Analyser: Laser Diffraction

Sample Volume: 100ml (Hydro SM)

Measurement Range: 0.2 μ m – 5000 μ m

Vibratory Sieve Shaker AS 200 control

Measurement Range: 63 μ m – 1000 μ m

Sieving motion: throwing motion with angular momentum

Amplitude: 0.2 - 3 mm (digital); Time: 1 - 99 min

Sieve diameter: 200 mm



Zeiss Axioskop 2 & Zeiss Stemi2000C

Optical – Polarizing – Stereomicroscope

LCD KL1500 Light source 2650K – 3300K

AxioCAM ICc3 for digital image capture



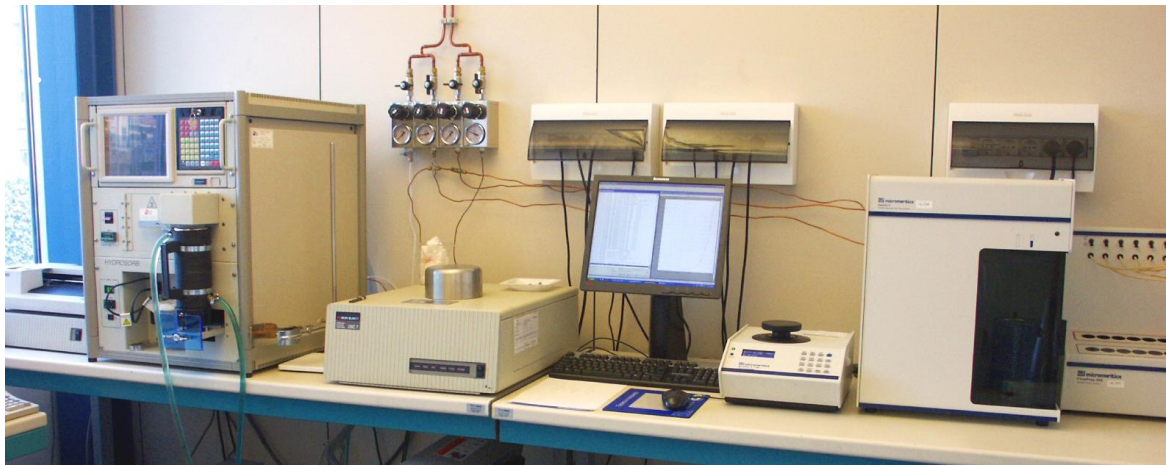
Erweka SVM102 & GLT

- Tap Density

- Bulk Density

- Flowability





Surface area, Moisture sorption & Thermal analysis



Micromeritics Gemini V & Floprep 060

Determination surface area and porosity.

Calculates single-point and multipoint BET and Langmuir surface areas, total pore volume, and micropore analysis by the t-method.

Minimum Surface Area: $0.01\text{m}^2/\text{g}$

Support Gases: Nitrogen and Helium



Micromeritics AccuPyc II 1340

High-precision volume measurements and true density calculations on a wide variety of powders, solids, and slurries.

Temperature Range: Ambient; Sample Volume: 10cm^3

Quantacrome Hydrosorb 1000

Measurement of adsorption and desorption water isotherms including BET, surface area calculations and heats of adsorption.

Temperature Range: $5^\circ\text{C} - 80^\circ\text{C}$

Sample Volume: 10cm^3



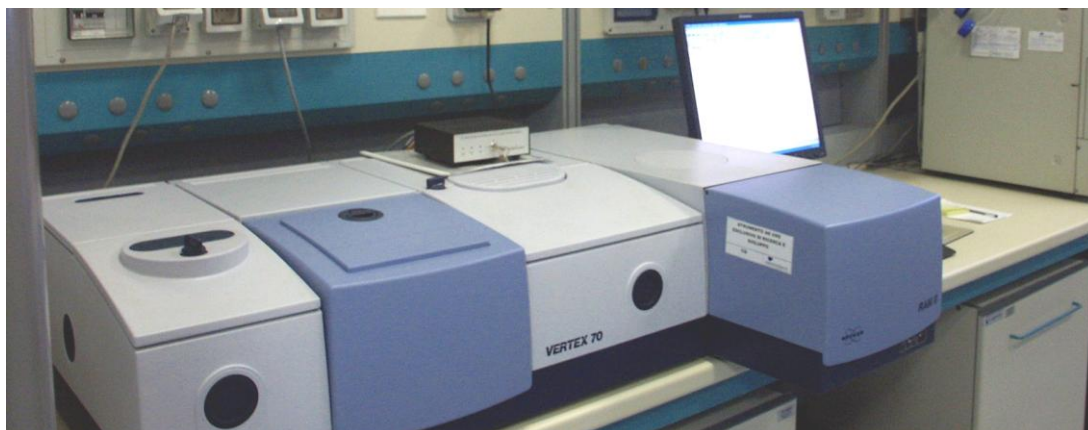
Perkin Elmer DSC 7

Measurement of thermal events such as melting, recrystallization, decomposition and glass transitions.

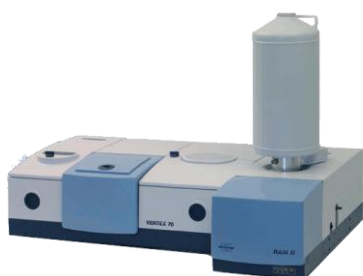
Determination of polymorph mixtures and compatibility with excipients.

Temperature Range: -20°C up to 500°C

Sample Volume: $30\mu\text{l}$



Spectroscopy & Chromatography



VERTEX 70 (FT-IR)/RAMII (FT-Raman) module

Fourier Transformed Infrared (IR) and Raman Spectroscopy.

Spectral range of 3600 – 50 cm⁻¹

Waters ACQUITY UPLC

Flow Rate Range: 0.010 to 2.000 mL/min,

System Delay Volume < 120µL,

Max Operating Pressure:

15,000 psi up to 1 mL/min

9000 psi up to 2 mL/min per pump



Waters ALLIANCE DAD + MICROMASS ZQ

Automated High Performance Liquid Chromatography (HPLC)

Mass spectrometry (Single Quadrupole)

Preformulation studies

We provide also services in the preformulation area to help a formulator to make informed decision during preclinical development.

- Physicochemical properties evaluation
- Drug-Excipient compatibility
- Solid dosage form formulation development
- Solution/suspension formulation development
- Topical formulation development
- Nano suspension development
- Amorphous solid dispersions

Monteresearch is a company of reference in the offer of specialized services for the Italian and European Markets in the areas of Pharmaceutical Research & Development.

Our main objective is to provide services and products according to our customers' needs. We are able to offer efficient solutions within the set deadlines.

We are experts in formulating and designing drug products manufacturing processes, in developing and validating analytical methods and in manufacturing and supplying the products required for the clinical trials of new drugs.



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